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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/797,485  
Filing Date: March 09, 2004  
Appellant(s): SAADAT ET AL.

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Johney U. Han  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed January 20, 2011 appealing from the Office action mailed February 23, 2010.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 67-71, 73-74, 76-80, 82-84, 92 and 94-96.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

5,251,611	Zehel et al.	10-1993
3,897,775	Furihata	8-1975
5,916,147	Boury	6-1999

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 67-71, 73-74, 76-80, 82-83, and 95-96 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,251,611 to Zehel et al.

**In regards to claims 67**, Zehel et al. disclose an endoluminal apparatus 1 comprising: an elongated main body 11 having a proximal end, a distal end, a longitudinal axis and at least one lumen 17 extending through the main body the main body comprising a single tube having at least a first section near the proximal end and a second section 12 near the distal end (see Fig. 1), and with the first section comprising a plurality of nested links 19 with substantially all adjacent links having mating surfaces that are in contact with but that are not connected to each other (see Fig. 3 and Col. 6, Lines 35-38) and having a plurality of first pullwire lumens 21, a plurality of first pullwires 20 routed through substantially each of the first pullwire lumens, with each of the first

pullwires being fixed to the elongated main body at a location at or near a distal end of the first section and at substantially a common point along the longitudinal axis of the main body, the first pullwires being substantially symmetrically spaced around the periphery of the nested links of the first section (see Figs. 2 and 4 and Col. 6, Line 60 – Col. 7, Line 15), a tensioning mechanism 16 operatively coupled to each of the first pullwires and adapted to impart tension force that is substantially evenly distributed to each of the first pullwires (see Col. 7, Lines 40-50), wherein the first section may be selectively switched between a substantially flexible condition and a substantially rigid condition (see Col. 7, Lines 1-14) wherein the second section is steerable relative to the first section (see Col. 5, Lines 1-27); and a scope being movable through the lumen relative to the elongated main body (see Col. 6, Lines 14-16 and Col. 8, Lines 40-42).

**In regards to claim 68**, Zehel et al. disclose an endoluminal apparatus, wherein the main body includes a torque transmitting feature which provides torque transmission between the proximal and distal ends while the main body is unlocked, to cause the main body to rotate substantially about its central axis (see Col. 5, Line 65 – Col. 6, Line 10).

**In regards to claim 69**, Zehel et al. disclose an endoluminal apparatus, comprises an atraumatic tip 40 having at least one opening corresponding to the at least one lumen (see Figs. 7-8 and Col. 9, Lines 20-40).

**In regards to claim 70**, Zehel et al. disclose an endoluminal apparatus, wherein the second section 12 may be switched between a flexible state and a substantially rigid state independently of the first section (see Col. 5, Lines 48-65). It is noted, that the

flexible device of the present invention, particularly the distal end thereof, may be optionally fitted with a wide variety of instruments for conducting a wide variety of exploratory, surgical or other procedures. For example, the device may be fitted with retractors to assist in retracting tissue away from the point of interest, ultrasonic devices, which for example, may be used in exploratory procedures, irrigation/suction devices for use in surgical procedures, tissue clipping devices, voice activated directional equipment, lock-on devices and the like. The procedures which may be conducted at the target point of the subject, once reached by the distal end of the flexible device, are likewise varied, and include, without limitation, visual inspection, polyp removal, biopsy, general surgery, photography, angioplasty, laser surgery and the like. Thus, as broadly as claimed, the distal end may be operated independently of the first section, and switched between a "flexible state" and a "rigid state".

**In regards to claim 71**, Zehel et al. disclose an endoluminal apparatus, with substantially each link in the first section configured to allow partial rotation relative to adjacent links and with the links arranged so that the first section can bend in at least two dimensions (see Figs. 5-6 and Col. 7, Line 63 – Col. 8, Line 10).

**In regards to claims 73-74**, Zehel et al. disclose an endoluminal apparatus, wherein the second section is steerable in up to three dimensions relative to the first section (see Col. 5, Lines 1-15).

**In regards to claim 76**, Zehel et al. disclose an endoluminal apparatus, further comprising at least two liners 10, 40 extending along a length of the elongated main body (see Figs. 7-8).

**In regards to claim 77**, Zehel et al. disclose an endoluminal apparatus, wherein at least one liner can transmit torque (see Col. 4, Lines 49-67).

**In regards to claims 78-79**, Zehel et al. disclose an endoluminal apparatus, further comprising a liner creating a lumen in the main body (see Figs. 8-9 and Col. 8, Lines 40-42). It is well known within the art to provide a hydrophilic coating on coaxial liners (see Col. 10, Lines 56-60).

**In regards to claim 80**, Zehel et al. disclose an endoluminal apparatus, wherein the scope comprises an endoscope extendable through the main body, with the scope having a steerable tip (see Col. 6, Lines 14-16 and Col. 8, Lines 40-42).

**In regards to claim 82**, Zehel et al. disclose an endoluminal apparatus, further comprising an insufflation lumen within the main body (see Col. 5, Lines 55-57).

**In regards to claim 83**, Zehel et al. disclose an endoluminal apparatus, wherein a first end of the endoscope is *positionable* in an off-axis position relative to the elongated main body such that a region of interest spaced apart from the elongated main body may be viewed at an angle via the endoscope (see Col. 6, Lines 11-19).

**In regards to claim 95**, Zehel et al. disclose an endoluminal apparatus, wherein the member positioned at a distal end of the first section is one of the plurality of nested link (see Fig. 2 and Col. 6, Lines 60-67).

**In regards to claim 96**, Zehel et al. disclose an endoluminal apparatus, wherein the tensioning mechanism comprises a pulley and wherein at least one of the first pullwires is routed though the pulley (see Col. 7, Lines 40-50).

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,251,611 to Zehel et al. in view of U.S. Patent No. 3,897,775 to Furihata.

**In regards to claim 84**, Zehel et al. disclose an endoluminal apparatus for a variety of endoscopic procedures (see rejection above) but are silent with respect to a Y-port located along the first section, wherein the Y-port is in communication with at least one lumen extending through the elongated main body. Furihata teach of an analogous apparatus have a Y-Port 37 located proximally along the endoscope apparatus (see Fig. 3 and Col. 4, Lines 35-55). It would have been obvious to one skilled in the art at the time the invention was made to include a Y-port in the apparatus of Zehel et al. to enable a user to introduce additional surgical instruments at a desired site within the body as taught by Furihata.

Claims 92 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,251,611 to Zehel et al. in view of U.S. Patent No. 5,916,147 to Boury.

**In regards to claims 92 and 94**, Zehel et al. disclose an apparatus 1 comprising: a shaft 11 comprising a single tube having a first section, a second section 12 and a longitudinal axis; a plurality of first links 19 in the first section, with adjacent first links pivotably abutting each other but not connected to each other (see Fig. 3 and Col. 6, Lines 35-38), and with substantially each first link having a contoured front surface adapted to engage with a contoured back surface of an adjacent first link and having a plurality of first pullwire lumens 21; a plurality of first pullwires 20 extending through substantially each of the first pullwire lumens, with each of the first pullwires



being fixed to the shaft at a location at or near a distal end of the first section and at substantially a common point along the longitudinal axis of the shaft, the first pullwires being substantially symmetrically spaced around the periphery of the first links of the first section (see Figs. 2 and 4 and Col. 6, Line 60 – Col. 7, Line 15); at least one second section steering wire (not shown) extending through substantially each of the first links and the second links (see Col. 4, Lines 34-36 and Col. 5, Lines 3-8); and at least one working lumen 17 extending through substantially each of the first links and the second links; and a scope extended through at least a portion of said at least one working lumen, said scope being moveable through said working lumen relative to said shaft (see Col. 6, Lines 14-16 and Col. 8, Lines 40-42). Zehel et al. teach that the distal end 12 may be optionally fitted with a wide variety of instruments for conducting a wide variety of exploratory, surgical or other procedures. For example, the device may be fitted with retractors to assist in retracting tissue away from the point of interest, ultrasonic devices, which for example, may be used in exploratory procedures, irrigation/suction devices for use in surgical procedures, tissue clipping devices, voice activated directional equipment, lock-on devices and the like (see Col. 5, Lines 48-65). However, Zehel et al. are silent with respect to a plurality of second links in the second section, with adjacent second links pivotably abutting each other but not connected to each other, and with substantially each second link having a contoured front surface adapted to engage with a contoured back surface of an adjacent second link. Firstly, Zehel et al. teach of the desirability of providing such "non-connected" links within a guiding apparatus (see Figs. 2-4 and Col. 6, Line 40-60, Col. 8, Lines 1-36). Secondly,

Boury teaches of an analogous endoscopic apparatus 10 comprising an elongated main body 30 having a proximal end 20, a distal end 16 and at least one lumen 142 extending through the main body the main body having at least a first section 36a near the proximal end and a second section 36d near the distal end, and with the first section comprising a plurality of nested links 140 with substantially all adjacent links having mating surfaces that are in contact with but that are not connected to each other (see Fig. 7 and Col. 13, Lines 43-67), wherein the first section may be selectively switched between a substantially flexible condition and a substantially rigid condition (see Col. 6, Lines 8-19) wherein the second section is steerable relative to the first section (see Fig. 2 and Col.7, Lines 47-56); and a scope being movable through the lumen relative to the elongated main body (see Col. 2, Lines 30-43). The proximal and distal segments are selectively moveable between an unlocked position wherein the locking segments are free to pivot with respect to one another and a locked position wherein the locking segments are constrained against relative movement. If so desired, the catheter can also include at least one control wire retained by the wall of the elongate tubular member, with the control wire extending proximally from the distal locking segment to a location proximal of the proximal locking segment. This will permit one to remotely engage the locking segments in their locked position. Thus, it would have been obvious to one skilled in the art at the time the invention was made to provide a distal most section in the apparatus of Zehel et al. that is constructed of a plurality of links pivotally abutting each other to provide a selectively formable guide tube for an

instrument, which allows a user to independently manipulate first and second sections of a guide tube as taught by Boury.

#### **(10) Response to Argument**

In regard to claim 67, Applicant states that Zehel et al. fail to disclose a main body "comprising a single tube". Examiner disagrees. Firstly, the claim clearly recites, "the main body **comprises** a single tube" having first and second sections. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," *is inclusive or open-ended and does not exclude additional, unrecited elements or method steps*. In *Gillette Co. v. Energizer Holdings Inc.*, 405F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to "a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades" encompasses razors with more than three blades because the transitional phrase "comprising" in the preamble and the phrase "group of" are presumptively open-ended. "The word comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." *Id.* (See MPEP 211.03). As such, the embodiments of Zehel disclosing a main body 11 with an additional inner conduit 10, fully meet the limitations of the claims. Furthermore, the "main body" is interpreted as being only the outer conduit 11, and thus the main is constructed of only a single tube. Inner conduit 10 is an additional device/instrument which is inserted therethrough (See Col. 4, Lines 49-57).

Applicant states that the embodiment shown in Figure 1 of Zehel et al. fails to include a "scope extended through" the main body lumen with the scope "being

moveable" through the lumen. Examiner disagrees. Main body 11 comprises a lumen 17 through which the inner flexible conduit 10 is *slidably disposed and free to travel* (see Col. 4, Lines 49-58). The conduit 10 has a hollow interior space 29 through which functional equipment, such as air lines, *optical fibers* and so on may pass (see Col. 8, Lines 40-42). Thus, with the inner conduit 10 arranged with optical fibers passing therethrough, an embodiment with a scope extended through the main body lumen and fully moveable therein would be provided. In other words, if surgical cutting tools are provided at the distal end 12 of main body 11 (see Col. 4, Lines 29-32), then a user would undoubtedly desire fiber optics within the hollow conduit 29 of slidable inner conduit 10 to provide a viewing platform to the system. Furthermore, Zehel clearly teaches that fiber-optic viewing capabilities may be provided through main body 11 or inner conduit 10 dependent upon the wide variety of surgical procedures to be performed (see Col. 5, Lines 48-67). Specifically, Zehel discloses that in addition to providing sufficient space for the inner flexible conduit 10 to slide within the main body 11, the annular space 9 between the inner wall of the conduit 11 and the outer wall of the inner flexible conduit 10 preferably provides sufficient room for deployment of, for example, additional functional devices, such as electrical wiring, optical fibers and the like which may be used at the distal end 12 of the device. Alternatively, or additionally, such functional devices, wires and optical fibers, and the like, may be passed through the interior space 29 of the inner flexible conduit 10 (see Col. 9, Lines 1-11). Lastly, Zehel clearly states "Because of the hollow, concentric nature of this preferred embodiment of the invention, standard endoscopic devices or, alternatively, the

individual conduits, cables, wires etc., that are associated with standard endoscopic devices, thus can occupy the center section 29" (see Col. 10, Lines 20-30). The device thus can be an add-on device for an existing endoscope or the stiffening feature may be included in the basic endoscope and one or more segmented concentric devices of the invention may be used around the endoscope. In other words, the inner conduit 10 would be the equivalent of an endoscope and the outer conduit 11 would act rigidizable insertion guide, nearly identical to the claimed invention.

The preferred embodiment of Zehel shown in Figure 1, comprises a section which is "steerable relative to the first section". This fact is not argued by the Applicant (see pg. 13 of the Appeal Brief).

The rejection of claim 67 is not reliant upon the second embodiment of Zehel et al. (seen in Figures 7-8) as argued by Applicant. Thus, the arguments are moot in view of the discussion provided above.

Regarding claims 84, 92 and 92, the Applicant fails to provide any new arguments regarding the claims, other than that those already presented under Section A in view Zehel and claim 67.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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